

Nuclear Regulatory Commission

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through 50 milligrams per square centimeter of absorber, shall be considered as a defective unit.

(c) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by paragraph (b) of this section, and proposed criteria for acceptance under those procedures. The Commission will approve the proposed alternative procedures if the applicant demonstrates that:

(1) They will consider defective any sampled device which has a leakage rate exceeding 0.1 percent of the original quantity of tritium or promethium-147 in any 24-hour period; and

(2) The operating characteristic curve or confidence interval estimate for the alternative procedures provides a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10.

(d) No person licensed under § 32.53 shall transfer to persons generally licensed under § 31.7 of this chapter:

(1) Any luminous safety device which has been tested and found defective under the criteria and procedures specified in this section, unless the defective units have been repaired or reworked and have then met the tests set out in paragraph (b) of this section; or

(2) Any inspection lot which has been rejected as a result of the procedures in § 32.110 or alternative procedures in paragraph (c) of this section, unless the defective units have been sorted and removed or have been repaired or reworked and have then met the tests set out in paragraph (b) of this section.

[30 FR 8192, June 26, 1965, as amended at 39 FR 22129, June 20, 1974; 39 FR 26397, July 19, 1974]

§ 32.56 Same: Material transfer reports.

Each person licensed under § 32.53 shall file an annual report with the Director of Nuclear Material Safety and Safeguards, by an appropriate method listed in § 30.6(a) of this chapter, which report must state the total quantity of tritium or promethium-147 transferred to persons generally licensed under § 31.7 of this chapter. The report must identify each general licensee by name, state the kinds and numbers of lumi-

nous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report must cover the year ending June 30 and must be filed within thirty (30) days thereafter.

[60 FR 3737, Jan. 19, 1995, as amended at 68 FR 58805, Oct. 10, 2003]

§ 32.57 Calibration or reference sources containing americium-241: Requirements for license to manufacture or initially transfer.

An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241, for distribution to persons generally licensed under § 31.8 of this chapter, will be approved if:

(a) The applicant satisfies the general requirements of § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of americium-241 in the source;

(2) Details of construction and design;

(3) Details of the method of incorporation and binding of the americium-241 in the source;

(4) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241, to demonstrate that the americium-241 contained in each source will not be released or be removed from the source under normal conditions of use;

(5) Details of quality control procedures to be followed in manufacture of the source;

(6) Description of labeling to be affixed to the source or the storage container for the source;

(7) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the source.

(c) Each source will contain no more than 5 microcuries of americium-241.

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(d) The Commission determines, with respect to any type of source containing more than 0.005 microcurie of americium-241, that:

(1) The method of incorporation and binding of the americium-241 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

(2) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by § 32.102, Schedule C, of this part.

[30 FR 8192, June 26, 1965, as amended at 43 FR 6923, Feb. 17, 1978]

§ 32.58 Same: Labeling of devices.

Each person licensed under § 32.57 shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:¹

The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—
THIS SOURCE CONTAINS AMERICIUM-241. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

(Name of manufacturer or initial transferor)

(Sec. 161, as amended, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201); sec. 201, as amended, Pub. L. 93-438, 88 Stat. 1243 (42 U.S.C. 5841))

[30 FR 8192, June 26, 1965, as amended at 40 FR 8786, Mar. 3, 1975; 43 FR 6923, Feb. 17, 1978]

§ 32.59 Same: Leak testing of each source.

Each person licensed under § 32.57 shall perform a dry wipe test upon each source containing more than 0.1 microcurie of americium-241 prior to transferring the source to a general li-

¹Sources licensed under § 32.57 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

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censee under § 31.8 of this chapter. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.005 microcurie of americium-241. If any such test discloses more than 0.005 microcurie of radioactive material, the source shall be deemed to be leaking or losing americium-241 and shall not be transferred to a general licensee under § 31.8 of this chapter.

[30 FR 8192, June 26, 1965]

§ 32.60 [Reserved]

§ 32.61 Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer.

An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under § 31.10 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of strontium-90 in the device;

(2) Details of construction and design of the source of radiation and its shielding;

(3) Radiation profile of a prototype device;

(4) Procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use;

(5) Details of quality control procedures to be followed in manufacture of the device;

(6) Description of labeling to be affixed to the device;

(7) Instructions for handling and installation of the device;